REMARKS

Claims 1-11, 13-21 are pending, and claims 2-3 are under consideration. Applicants have amended the specification to correct clerical errors or informalities, and claim 2 to make it independent by recitations of claim 1. No issues of new matter are believe to have been raised and entry of the amendments and favorable reconsideration are respectfully requested.

Applicants further submit that the amendments have obviated the objections to the specification and to Claim 2.

Claim rejection under 35 U.S.C. § 112, ¶ 1

The Office Action rejected Claim 2 for alleged lack of enablement, stating that (1) the claim is broad but only a specific sequence has been described, and (2) because of the unpredictability of the art of protein chemistry, it would require undue experimentation to screen variants to determine whether they have the claimed IPAS activity. Applicants respectfully traverse.

As an initial matter, applicants submit that the Office Action misconstrued Claim 2 by stating that "[t]he claim is drawn to an isolated mammalian IPAS polypeptide encoded by any nucleic acid, which broadly encompasses a whole universe of encoded polypeptides," (page 5, lines 12-13), and that "the claim [is] broadly drawn to any encoded IPAS polypeptide with or without the biological properties representative of what is claimed . . ." Probably due to this overly broad reading of Claim 2, the Office Action asserted that Claim 2 lacks enablement under 35 U.S.C. § 112, first paragraph.

When properly construed, however, Claim 2, encompasses only a limited genus of polypeptides encoded by nucleic acid molecules that hybridize under stringent conditions with a complementary sequence of a nucleotide sequence comprising SEQ ID NO: 2. Furthermore, the claim requires that the polypeptide encoded retains a biological activity of mammalian IPAS.

Given the disclosure of "stringent conditions" in the specification (see e.g. page 7, lines 17-21), and the teachings in the specification and in the prior art regarding screening polypeptides for IPAS activity, it is readily apparent the Claim 2 is sufficiently enabled.

The Office Action correctly articulates the proper legal standard for enablement analysis, i.e. whether any experimentation, if needed, is undue. The Office Action seems to argue that due to the unpredictability of the art of protein chemistry, a lot of experimentation may be needed to screen for polypeptides that retain the requisite IPAS activity. However, as stated in MPEP §2164.04,

> The quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. "[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). "'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.'" *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Time and expense are merely factors in this consideration and are not the controlling factors. *United States v. Telectronics Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), cert. denied, 490 U.S. 1046 (1989).

Applicants respectfully submit that merely routine experimentation is required to arrive at the variants of SEQ ID NO: 2 that remain hybridized thereto, and to test whether the polypeptides encoded thereby have the requisite biological activities. The art of nucleotide hybridization has long become well-established and its techniques routine, so it only requires minimum and simple effort to determine which nucleic acid molecular would satisfy the recited hybridization conditions. In fact, such determination can even be done theoretically using well-established formula without any need of actual experimentation.

Furthermore, the specification and the prior art provide ample guidance as to how to screen polypeptides encoded by the nucleic acid molecules to determine if they retain the requisite IPAS activity. Toward that end, applicants direct the Examiner's attention to Examples 5 and 6 of the instant specification. To further establish that only routine experimentation is needed to conduct such screening, applicants submit a Declaration under 37 C.F.R. § 1.132, by one of the inventors, Dr. Poellinger. In the declaration, Dr. Poellinger

explains in detail how such screening can be conducted according to well-established and well-known methods, and that such screening only require general and routine skills of a lab technician or a graduate student.

In summary, applicants respectfully submit that no undue experimentation is needed to make and use the polypeptides as claimed and that the specification provides sufficient guidance regarding the routine experimentation needed for the screening. Accordingly, applicants respectfully request the withdrawal of the claim rejection, and an early indication of allowability of both claims.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #056187/51594US).

Respectfully submitted,

July 15, 2003

Kening Li, Ph.D.
Registration No. 44,872
J. D. Evans
Registration No. 26,269

CROWELL & MORING, LLP
Intellectual Property Group
P.O. Box 14300
Washington, DC 20044-4300
Telephone No.: (202) 624-2500
Facsimile No.: (202) 628-8844
JDE:KL:tlm